

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Claims 95-115 and 125-135 are pending. Claims 95 and 102 have been amended to incorporate the limitation of claim 97. Claim 97 has been canceled. Support for the amendment is found, for example, on page 5, lines 20-21. Claim 102 has also been amended to specify that the PHA in the film has a Mw greater than 420,000. Support for the amendment is found, for example, on page 5, lines 16-17.

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 102 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Examiner alleges that claim 102 is indefinite because it is not clear whether the cited molecular weight is the molecular weight of the pellet or the film. Without making any admissions and solely for the purpose of facilitating prosecution, claim 102 has been amended to specify that the PHA in the film has a Mw greater than 420,000, as suggested by the Examiner. Support for the amendment is found, for example, on page 5, lines 16-17.

Rejection Under 35 U.S.C. § 103

Claims 95, 96, 102-115, and 125-135 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,061,743 to Herring *et al.* ("Herring"), in view of U.S. Patent No. 5,502,273 to Bright *et al.* ("Bright") or U.S. Patent No. 5,753,782 to Hammond *et al.* ("Hammond"), further in view U.S. Patent No. 5,217,803 to McBride *et al.* ("McBride") or U.S.

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Patent No. 5,300,576 to Nemphos *et al.* ("Nemphos"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention; however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held to be improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999).

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To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Analysis

In the office action mailed on July 10, 2006, the Examiner stated that the incorporation of any of the limitations of claims 97-101, 134, or 135 would obviate this rejection. Claims 95 and 102, the independent claims, have been amended to incorporate the limitation of claim 97; wherein the PHA film has a draw ratio between about 2 and 7. Claim 97 has been canceled. It is therefore understood that all of the claims are patentable over the prior art discussed below.

Herring

Herring discloses PHA compositions comprising a PHA and a nucleating agent composed of a combination of an organophosphonic or organophosphoric acid or ester with an oxide, hydroxide, or carboxylate of a metal of Group I to V. Examples 1-4 describe extruding HB polymers containing varying amounts of HV monomer. Example 5 describes injection molding a formulation containing HB polymer containing 17% HV monomer. Herring is concerned with the use of nucleants to increase the rate of crystallization. Herring does not disclose or suggest the use of a thermal stabilizer to inhibit the thermal degradation of PHA

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compositions during film formation. Herring does not disclose a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 and wherein the film has a draw ratio of between about 2 and 7. Herring does not disclose blown or cast films having a draw an elongation at break of greater than 65%, or a tensile strength greater than 50 Mpa (claims 98 and 100). Herring discloses tensile strength (Young's modulus) data for molded tensile bars (Table 6), but nor for blown or cast free-standing films.

Bright

Bright describes a plant having a recombinant genome which contains one or more of the genes encoding enzymes critical to the polyhydroxyalkanoate biosynthetic pathway, which produces polyhydroxyalkanoate polymer. Bright does not disclose or suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 and wherein the film has a draw ratio of between about 2 and 7 nor methods of making thereof.

Hammond

Hammond describes polyester compositions comprising a biodegradable polyester and a plasticizing quantity of at least one plasticizer selected from the group consisting of high boiling esters of polybasic acids, phosphoric acid derivatives, phosphorous acid derivatives, phosphonic acid derivatives, substituted fatty acids, high boiling glycols, polyglycols, polyoxyalkylenes, and glycerol (abstract). Hammond does not disclose or suggest blown or cast free-standing films

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comprising melting a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 and wherein the film has a draw ratio of between about 2 and 7 nor methods of making thereof. Hammond describes extruding compositions containing PHBV and a nucleant to form a single lacc, which is dried and cut into granules. The granules are injection molded into dumbbell shaped tensile bars (Examples 1-3). There is no disclosure in Hammond of extruding a PHA and a thermal stabilizer to form pellets and then extruding the pellets to form a film, wherein the film has a molecular weight greater than 420,000. Therefore, the claims, as amended, are novel over Hammond.

McBride

McBride describes biodegradable films that comprise a blend of an interpenetrated network of destructureized starch with ethylene/acrylic acid copolymers or ethylene/vinyl alcohol copolymers, and an aliphatic polyester such as polycaprolactone. In a preferred embodiment, the aliphatic polyester is polycaprolactone with an initial molecular weight of about 80,000 grams/mole (col. 5, lines 37-39). The claims, as pending, are not directed to interpenetrated networks. McBride does not disclose or suggest a blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a Mw greater than 420,000 and wherein the film has a draw ratio of between about 2 and 7 nor methods of making thereof. In fact, McBride is silent regarding the molecular weight of the PHA in the film.

Nemphos

Nemphos describes polymer blends having a T_g of not less than 62°C, comprising a polyhydroxyalkanoate having a molecular weight greater than 40,000 and one or more polymers having a T_g from 75°C to 200°C (col. 2, lines 28-50). Suitable PHAs are described at col. 3, lines 3-16). Nemphos discloses that pellets of the polymer blends can be injection molded or thermoformed to produce various articles such as sheets and containers. Nemphos, however, does not disclose a method of producing blown or cast free-standing films comprising melting a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 and wherein the film has a draw ratio of between about 2 and 7. In fact, Nemphos does not disclose or suggest PHA films nor methods of making thereof.

Herring In View of Bright or Hammond Further In View of McBride or Nemphos

One of ordinary skill in the art would not be motivated to modify the references as required to produce the claimed compositions and methods. Additionally, if one did combine the references, one would not arrive at the claimed compositions and methods. None of the references cited by the Examiner disclose or suggest a blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a Mw greater than 420,000 and wherein the film has a draw ratio of between about 2 and 7 nor methods of making thereof. As noted in the specification, extruded PHAs having molecular weights greater than about 420,000 provide a desirable combination of melt strength during initial film formation and subsequent drawability sufficient for use in stable blown film and cast film processes (page 19,

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lines 25-27). Further, applicants disclose that higher molecular weight PHA films (i.e. greater than 420,000) could be produced without encountering processing difficulties due to unacceptably high viscosities. However, one of ordinary skill in the art would not have expected PHA films having a molecular weight greater than 420,000 to exhibit the physical properties disclosed by the applicants. The references cited by the Examiner do not disclose or suggest that higher molecular weight PHA films would exhibit the desirable combination of melt strength during initial film formation and subsequent drawability for use in stable blown and cast film processes described by the applicants. Therefore, claims 95-96, 98-115, and 125-135, as amended, are not obvious over Herring in view of Bright or Hammond further in view of McBride or Nemphos.

Double Patenting Rejection

Claims 95-115 and 125-135 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,127,512.

This rejection is improper based on a comparison of independent claims 95 and 102, as amended, with claims 1-11 of the '521 patent, as shown below.

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Pending Claims	Claims of the '512 Patent
<p>95. A blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a Mw greater than 420,000 and wherein the film is made from a pellet composition comprising the PHA and a thermal stabilizer, wherein the draw ratio of the film is between about 2 and 7.</p> <p>102. A method of producing a blown or cast free-standing film, comprising melting a pellet composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000, and wherein the film has a draw ratio of between about 2 and 7.</p>	<p>I. Polyester pellet composition comprising a polyhydroxyalkanoate (PHA) having a molecular weight (Mw) of greater than about 470,000 and a plasticizing quantity of at least one plasticizer selected from the group consisting of:</p> <p>A. high boiling point esters selected from:</p> <p>(i) phthalates and isophthalates of the formula:</p> <div data-bbox="582 527 728 646" data-label="Chemical-Block"> </div> <p>where R₁ is C₁₋₂₀ alkyl cycloalkyl or benzyl;</p> <p>(ii) citrates of the formula:</p> <div data-bbox="540 729 754 889" data-label="Chemical-Block"> </div> <p>where R₁ is hydrogen or C₁₋₁₀ alkyl, and R₂ is C₁₋₁₀ alkyl, C₁₋₁₀ alkoxy or C₁₀ alkoxyalkyl;</p> <p>(iii) adipates of the formula R₁ --O--C(O)--(CH₂)₄--C(O)--OR₂ where R₁ and R₂ which may be the same or different are C₂₋₁₂ alkyl or C₂₋₁₂ alkoxyalkyl;</p> <p>(iv) sebacates of the formula R₁ --C(O)--(CH₂)₈--C(O)--O--R₁ where R₁ is C₂₋₁₅ alkyl or C₂₋₁₅</p>

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	<p>alkoxyalkyl;</p> <p>(v) azelates of the formula $R_1-O-C(O)-(CH_2)_7-C(O)-R_1$ where R_1 is C_{2-12} alkyl, benzyl, or C_{2-12} alkoxyalkyl;</p> <p>B. alkyl ethers/esters of the formula $R_2-O-CH_2-CH_2)_n-O-R_1$ where R_1 is alkyl or $C(O)-alkyl$, R_2 is alkyl and n is 2 to 100; or where R_1 is hydrogen and either: R_2 is alkylphenyl where the alkyl is C_{2-12} alkyl, and n is 1 to 100; or R_2 is $CH_3-(CH_2)_{10}-C(O)-$ and n is 5, 10, or R_2 is $CH_3-(CH_2)_7-CH=CH-(CH_2)_7-C(O)-$ and n is 5 or 15;</p> <p>C. epoxy derivatives of the formula $CH_3-(CH_2)_n-A-(CH_2)_n-R$ in which the A is an alkene containing one or more double bonds (i.e. unsaturated fatty acids), n is 1 to 25 and R is C_{2-15} alkyl; or epoxy derivatives of triglycerides containing one or more double bonds per fatty acid chain with chain lengths from C_{6-26}.</p> <p>D. substituted fatty acids selected from the group consisting of sorbitan monolaurate, sorbitan monooleate, poly(oxyethylene)(20)Sorbitan monolaurate, poly(oxyethylene)(4)lauryl ether, and butyl acetyl ricinoleate; and</p> <p>E. polymeric esters of the formula $-O-C(O)-R_1-C(O)-O-R_2-O-$ in which R_1 and R_2 are both independently C_{2-12} alkylene, or R_2 may be derived from a diol.</p> <p>2. Polyester composition according to claim 1 wherein the polymeric ester is selected from glutaric polyesters having molecular weights</p>
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(Mw) from 2000 to 20,000, adipic polyesters having a molecular weight (Mw) from 200 to 20,000, succinic polyesters, sebacic polyesters having a molecular weight (Mw) from 4000 to 10,000, lactone copolymers of the formula $\{--(O)--C(O)--R_1--C(O)--O--R_2--O\}_m--[(C(O)--R_3--O--)]_n$ where R_1 and R_2 are both independently C_{2-12} , alkylene, or R_2 may be derived from a diol, and R_3 is $--(CH_2)_5--$ (based on caprolactone), polyesters of mixed adipic, glutaric and succinic acids, polycaprolactone triol.

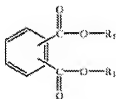
3. Polyester composition according to claim 1 wherein the polymeric ester is selected from poly(1,3-butylene glycol-co-1,2-propylene glycol adipic acid) terminated with 2-ethylhexanol, poly(neopentyl glycol-co-1,4-butylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,3-butylene glycol adipic acid) unterminated, poly(1,2-propylene glycol adipic acid-co-phthalic acid) terminated with 2-ethylhexanol, poly(neopentyl glycol adipic acid) terminated with 2-ethylhexanol, poly(1,2-propylene glycol adipic acid-co-phthalic acid) terminated with 2-ethylhexanol, poly(1,2-propylene glycol-co-1,4-butylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,3-butylene glycol adipic acid) terminated with mixed fatty acids, poly(1,2-propylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,2-propylene glycol-co-1,4-butylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,4-butylene glycol adipic acid), or poly(1,4-butylene glycol-co-ethylene glycol adipic acid).

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4. A method of producing a shaped polymeric object comprising melting a composition comprising a polyhydroxyalkanoate (PHA) having a molecular weight of greater than about 470,000 and producing a shaped object therefrom by extrusion, molding, coating, spinning or calendaring operations, wherein the composition has a plasticizing quantity, of at least one plasticizer selected from the group consisting:

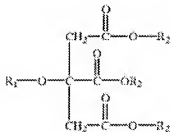
A. high boiling point esters selected from:

(i) phthalates and isophthalates of the formula:



where R_1 is C_{1-20} alkyl cycloalkyl or benzyl;

(ii) citrates of the formula:



where R_1 is hydrogen or C_{1-10} alkyl, and R_2 is C_{1-10} alkyl, C_{1-10} alkoxy or C_{10} alkoxyalkyl;

(iii) adipates of the formula $\text{R}_1-\text{O}-\text{C}(=\text{O})-(\text{CH}_2)_4-\text{C}(=\text{O})-\text{OR}_2$ where R_1 and R_2 which may be the same or different are C_{2-12} alkyl or C_{2-12} alkoxyalkyl;

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(iv) sebacates of the formula $R_1 - (O) - (CH_2)_8 - (O) - O - R_1$ where R_1 is C_{2-15} alkyl or C_{2-15} alkoxyalkyl;

(v) azelates of the formula $R_1 - (O) - (CH_2)_7 - (O) - R_1$ where R_1 is C_{2-12} alkyl, benzyl, or C_{2-12} alkoxyalkyl;

B. alkyl ethers/esters of the formula $R_2 - (O) - CH_2 - (CH_2)_n - O - R_1$ where R_1 is alkyl or $C(O) -$ alkyl, R_2 is alkyl and n is 2 to 100; or where R_1 is hydrogen and either: R_2 is alkylphenyl where the alkyl is C_{2-12} alkyl, and n is 1 to 100; or R_2 is $CH_3 - (CH_2)_{10} - (O) -$ and n is 5, 10, or R_2 is $CH_3 - (CH_2)_7 - CH=CH - (CH_2)_7 - (O) -$ and n is 5 or 15;

C. epoxy derivatives of the formula $CH_3 - (CH_2)_n - A - (CH_2)_n - R$ in which the A is an alkene containing one or more double bonds (i.e. unsaturated fatty acids), n is 1 to 25 and R is C_{2-15} alkyl; or epoxy derivatives of triglycerides containing one or more double bonds per fatty acid chain with chain lengths from C_{6-26} .

D. substituted fatty acids selected from the group consisting of sorbitan monolaurate, sorbitan monooleate, poly(oxyethylene)(20)Sorbitan monolaurate, poly(oxyethylene)(4)lauryl ether, and butyl acetyl ricinoleate; and

E. polymeric esters of the formula $-O - (O) - R_1 - (O) - O - R_2 - O -$ in which R_1 and R_2 are both independently C_{2-12} alkylene, or R_2 may be derived from a diol.

5. The method of claim 4 wherein the

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polymeric ester is selected from glutaric polyesters having molecular weights (Mw) from 2000 to 20,000, adipic polyesters having a molecular weight (Mw) from 200 to 20,000, succinic polyesters, sebacic polyesters having a molecular weight (Mw) from 4000 to 10,000, lactone copolymers of the formula $[-(O)-C(O)-R_1-C(O)-O-R_2-O-]_m-[(C(O)-R_3-O-)]_n$ where R_1 and R_2 are both independently C_{2-12} , alkylene, or R_2 may be derived from a diol, and R_3 is $-(CH_2)_5-$ (based on caprolactone), polyesters of mixed adipic, glutaric and succinic acids, polycaprolactone triol.

6. The method of claim 4 wherein the polymeric ester is poly(1,3-butylene glycol-co-1,2-propylene glycol adipic acid) terminated with 2-ethylhexanol, poly(neopentyl glycol-co-1,4-butylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,3-butylene glycol adipic acid) unterminated, poly(1,3-butylene glycol adipic acid) unterminated, poly(1,2-propylene glycol adipic acid-co-phthalic acid) terminated with 2-ethylhexanol, poly(neopentyl glycol adipic acid) terminated with 2-ethylhexanol, poly(1,2-propylene glycol adipic acid-co-phthalic acid) terminated with 2-ethylhexanol, poly(1,2-propylene glycol-co-1,4-butylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,3-butylene glycol adipic acid) terminated with mixed fatty acids, poly(1,2-propylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,2-propylene glycol-co-1,4-butylene glycol adipic acid) terminated with 2-ethylhexanol, poly(1,4-butylene glycol adipic acid), or poly(1,4-butylene glycol-co-ethylene glycol adipic acid).

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	<p>7. The method of claim 4 wherein the shaped object is a blown film.</p> <p>8. A shaped object produced according to claim 4.</p> <p>9. A shaped object produced according to claim 5.</p> <p>10. A shaped object produced according to claim 6.</p> <p>11. A shaped object produced according to claim 7.</p>
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The claims of the present application are directed to a blow or cast free standing film containing a PHA and a thermal stabilizer, wherein the PHA in the film is greater than 420,000 and wherein the film has a draw ratio between about 2 and 7, and methods of making thereof. In contrast, the claims of the '512 patent are directed to a polyester pellet composition containing a PHA and a plasticizer, shaped articles formed from the polyester pellet composition, and methods of making thereof. The claims of the '521 patent do not define a blow or cast free standing film containing a PHA and a thermal stabilizer, wherein the Mw of the PHA in the film is greater than 420,000 and wherein the film has a draw ratio between about 2 and 7. A plasticizer lowers the glass transition temperature of the polymer, which softens the polymer making it more flexible. A thermal stabilizer reduces the molecular weight degradation of the

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polymer during pellet and film formation. Accordingly, claims 95-96, 98-115 and 125-135 are not obvious over claims 1-11 of the '512 patent.

Allowance of claims 95-96, 98-115 and 125-135, as amended, is respectfully solicited.

Respectfully submitted,

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